SMC Standard SMC-S-003
8 May 2015

Supersedes:
SMC-S-003 (2008)

Air Force Space Command

SPACE AND MISSILE SYSTEMS CENTER STANDARD

QUALITY SPACE AND LAUNCH REQUIREMENTS ADDENDUM TO AS9100C

APPROVED FOR PUBLIC RELEASE; DISTRIBUTION IS UNLIMITED

FOREWORD

1. This standard defines the Government's requirements and expectations for contractor performance in defense system acquisitions and technology developments.

2. This revised SMC standard comprises the text of The Aerospace Corporation report number TR-RS-2015-00003, entitled *Quality Space and Launch Requirements Addendum to AS9100C.* The present approach to documenting additional space and launch quality assurance requirements is substantially different from the superseded document as they are now written as an addendum to the industry consensus standard rather than as a stand-alone standard. Details of other requirement changes are documented in TR-RS-2015-0003.

3. Beneficial comments (recommendations, changes, additions, deletions, etc.) and any pertinent data that may be of use in improving this standard should be forwarded to the following addressee using the Standardization Document Improvement Proposal appearing at the end of this document or by letter:

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SPACE AND MISSILE SYSTEMS CENTER
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4. This standard has been approved for use on all Space and Missile Systems Center/Air Force Program Executive Office - Space development, acquisition, and sustainment contracts.

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Figure 1. How this standard builds on the AS9100 model. 2

1. Introduction

1.1 Background

Because of the highly complex nature of satellites and launch vehicles, coupled with the inability to repair vehicles on orbit, stringent quality and reliability requirements are levied on contractors to ensure that products will meet their intended lifecycle.

This standard assumes the contractor is certified to AS9100. AS9100 provides the requirements of "what" should be included in a Quality Management System (QMS) suitable for the production of aerospace product. This standard incorporates best practices of the space industry and therefore provides many of the requirements to supplement AS9100 for high reliability space programs.

1.2 Application

The requirements of this standard either in full or as appropriately tailored shall be levied on prime contractors, subcontractors, and their sub-tier suppliers of space and launch vehicles. As this standard provides the "how-to's" of implementing the standards ISO9001 and AS9100 but does not duplicate the requirements of those standards, it is preferred that subcontractors/suppliers be certified to the latest version of ISO9001 or AS9100.

It is understood that not all suppliers may be compliant to AS9100 or perhaps even to ISO 9001. Section 7 provides requirements for selecting and monitoring the performance of a supplier. Certification to these standards is encouraged, but will depend on the product being supplied, uniqueness of the capability of the supplier, costs of acquiring certification, and the criticality of the work. A supplier that is not certified increases risk and the supplier requirements in Section 7 become even more important and will be more difficult to enforce.

In the event the subcontractor/supplier is not certified to ISO9001 or AS9100, the contractor shall focus on obtaining conforming material and tailor this document for the supplier as required. The contractor shall assume the responsibility for satisfying ISO9001 or AS9100 requirements for purchased materials and parts from a supplier not certified to either standard. This may be accomplished through record keeping, additional testing, purchasing documentation, contractor second party audits, etc.

1.3 Structure of this Standard

A concerted effort was made to not repeat requirements provided in AS9100. In addition the requirements of this standard were aligned with those of AS9100 using the seven sections of AS9100:

2. References
3. Terms and definitions
4. QMS
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement, analysis, and improvement.

Therefore Sections 2 through 8 of this standard address the same topics as Sections 2 through 8 respectively of AS9100.

The requirements of this standard go beyond AS9100. It is recognized that the changes in technology in business systems may enable contractors to accomplish the requirements in a multitude of ways. Therefore, this standard presents what is believed to be implementations of best practices but recognizes that contractors may have alternative implementations. For any alternative approach which achieves the same end, the contractor shall demonstrate that all requirements are met by the alternative implementation. These best practice implementations are provided in paragraphs enclosed by a border.

By way of example (see implementation comments at the end of clause 4.4.4), this standard requires a contractor to provide a vehicle level data package. The package should contain the complete integration and test history. The implementation comment states that retrieving the data via on-line access to multiple databases is an acceptable alternative to a complete printed product as long as data access is given to reviewers and data is retrievable over the life of the program.

1.4 Mapping of this Standard to AS9100

AS9100 provides a plan-do-check-act model of a process-based QMS. This is shown in the process map below as indicated by the unshaded rectangles (Figure 1). This standard touches almost every aspect of that model by indicating additional requirements in the shaded boxes.

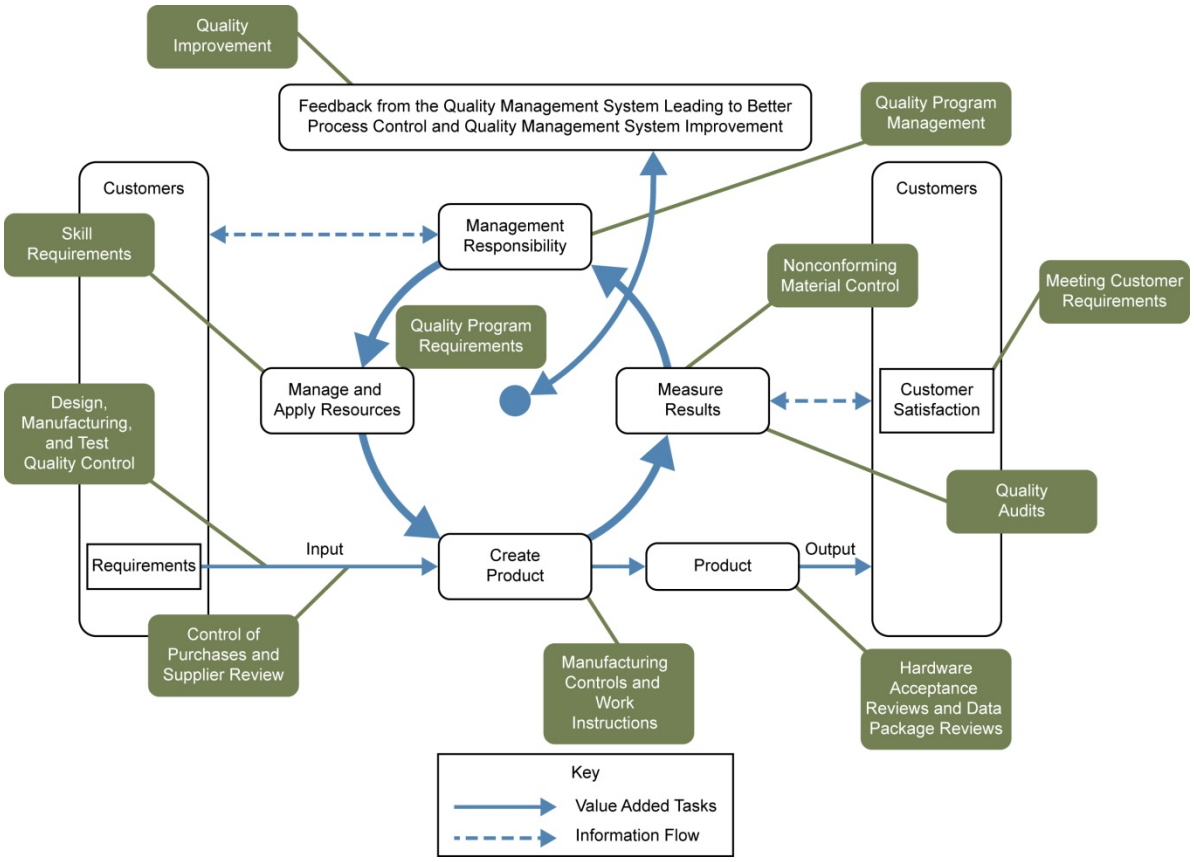

Figure 1. How this standard builds on the AS9100 model.

1.5 Tailoring Guidance

1.5.1 General

This standard is applied at the discretion of the customer in accordance with contractual direction. In each application, this standard may be tailored to the specific requirements of a particular program, program phase, or contractual structure as directed by the customer. Tasks that add unnecessary costs, data, and any factors that do not add value to the process or product shall be eliminated. Tailoring takes the form of deletion (removal of tasks not applicable), alteration (modifying tasks to more explicitly reflect the application to a particular effort), or addition (adding tasks to satisfy program requirements).

1.5.2 Tailoring Considerations

The quality requirements discussed in this standard are applicable to all programs, irrespective of complexity, risk, or scope. However, the extent of QMS requirements will vary depending on the specific system being developed as well as contractual requirements. Tailoring of this guidance informs the customer of the contractor's choice of tools, measurements, metrics, and specific quality assurance methods and tasks. The contractor's tailoring of this guidance shall be subject to the customer's direction and approval. The objectives of the contract define the breadth and depth of the quality assurance process for each specific procurement.

1.5.3 Requirements Duplication

To minimize duplication of requirements between standards, an effort was made to exclude requirements that are addressed in other space or launch vehicle standards that are frequently put on contract. For example, while physical and functional configuration audits (PCA and FCA) are an integral component to quality assurance, they are addressed in TR-RS-2006-00002, *Configuration Management*. They are mentioned in this standard but the detail is provided in TR-RS-2006-00002.

To preclude an inadvertent elimination of a quality requirement from a related standard, this standard will mention the requirement by reference to the parent standard. The contracting authority responsible for tailoring quality standards for a program, will ensure that the following quality topics are addressed by contract requirements. If the topics have been purposely eliminated, the rationale for elimination will be included in the tailored version of this standard in the clauses listed below.

Clause	Topic	Standard
1.5.3 7.1.1	PCA and FCA CDR and PDR	TR-RS-2009-00021, *Technical Reviews and Audits for Systems, Equipment, and Computer Software* [also published as SMC-S-021]
1.5.3 7.1.1	PCA and FCA CDR and PDR	TR-RS-2013-00001, *Systems Engineering Requirements and Products* [Also published as SMC-S-001]
1.5.3 7.4.1.1	PCA and FCA Configuration	TR-RS-2006-00002, *Configuration Management* [also published as SMC-S-002]
7.6.3.2. 3	Software Surveys	TR-RS-2015-00012, *Software Development Standard for Mission Critical Systems* [also published as SMC-S-012]
8.7.2	FRB	TR-RS-2007-00013, *Reliability Program Requirements for Space* [also published as SMC-S-013]

Clause	Topic	Standard
8.7.2	Failure Analysis	TR-RS-2013-00009, *Parts, Materials, and Processes Control Program for Space Vehicles* [also published as SMC-S-009]
8.7.2	Failure Analysis	TR-RS-2011-00011, *Materials, and Processes Control Program for Expendable Launch Vehicles* [also published as SMC-S-011]

2. References

2.1 Applicable Documents

Unless otherwise specified, the applicable issues shall be those on the procuring activity's current list of compliance standards at the date of solicitation. When any of the following documents conflict with this standard, this standard shall take precedence.

ANSI/NCSL Z540.3	*Requirements for the Calibration of Measuring and Test Equipment* (3 August 2006)
ANSI/NCSL Z540-1	*Calibration Laboratories and Measuring and Test Equipment – General Requirements* (1994)
ISO 9001:2008	*Quality management systems – Requirements* (2008)
ISO/IEC 17025:2005	*General requirements for the competence of testing and calibration laboratories*
MIL-STD-45662A	*Calibration Systems Requirements* (Cancelled 27 February 1995)
SAE AS9015	*Supplier Self Verification Process – Delegation Programs* (9/26/2007)
SAE AS9100C	*Quality Management Systems – Requirements for Aviation, Space and Defense Organizations* (January 2009)
TR-RS-2006-00002 (aka SMC-S-002)	*Configuration Management*
TR-RS-2007-00013 (aka SMC-S-013)	*Reliability Program Requirements for Space Systems*
TR-RS-2009-00021 (aka SMC-S-021)	*Technical Reviews and Audits for Systems, Equipment, and Computer Software*
TR-RS-2011-00011 (aka SMC-S-011)	*Parts, Materials, and Processes Control Program for Expendable Launch Vehicles*
TR-RS-2013-00001 (aka SMC-S-001)	*Systems Engineering Requirements and Products*
TR-RS-2013-00009 (aka SMC-S-009)	*Parts, Materials, and Processes Control Program for Space Vehicles*
TR-RS-2015-00012 (aka SMC-S-012).	*Software Development Standard for Mission Critical Systems*

2.2 Reference Documents

MIL-Q-9858A	*Quality Program Requirements (9 April 1959). Cancelled with Notice 2 dated 01 October 1996.*
MIL-STD-280A	*Definitions of Item Levels, Item Exchangeability, Models, and Related Terms (7 July 1969) Cancelled with Notice 2 dated 12 February 1998.*
MIL-STD-1520C	*Corrective Action and Disposition System for Nonconforming Material (27 June 1986) Cancelled with Notice 2 dated 27 February 1995.*
MIL-STD-1586A	*Quality Program Requirements for Space and Launch Vehicles (15 June 1989). Cancelled with Notice 1 dated 31 May 1995.*
ISO 14300-2:2011	*Space Systems – Program Management – Part 2: Product Assurance*
	Defense Manufacturing Management Guide for Program Managers (16 October 2012)
TOR-2005(8583)-3859 (aka SMC-S-003)	*Quality Assurance Requirements for Space and Launch Vehicles*

3. Acronyms and Definitions

3.1 List of Acronyms

ANSI	American National Standards Institute
ASIC	Application Specific Integrated Circuit
ASNT	American Society for Nondestructive Testing
CAB	Corrective Action Board
CDR	Critical Design Review
CDRL	Contract Data Requirements List
CI	Configuration Item
DCMA	Defense Contract Management Agency
ESD	Electro Static Discharge
FCA	Functional Configuration Audit
FRB	Failure Review Board
GIDEP	Government Industry Data Exchange Program
HAR	Hardware Acceptance Review
MR	Material Review
MRB	Material Review Board
MRR	Manufacturing Readiness Review
NCSL	National Conference of Standards Laboratories
NRO	National Reconnaissance Office
OCAP	Out of Control Action Plan
OCC	Out of Control Condition
OJT	On the Job Training
PA	Product Assurance
PCA	Physical Configuration Audit
PDR	Preliminary Design Review
PHS&T	Packaging, Handling, Storage, and Transportation
PM&P	Parts, Materials, and Processes
PR	Preliminary Review
QA	Quality Assurance
QIP	Quality Improvement Project
QMS	Quality Management System
QPP	Quality Program Plan
SMC	Space and Missile Systems Center
SME	Subject Matter Expert
SOW	Statement of Work
SPC	Statistical Process Control
SPO	System Program Office
SRP	Standard Repair Procedure
TRR	Test Readiness Review

3.2 Definitions

Certification. The act of documenting that a person, organization, process, equipment, etc., meets a set of requirements traceable to a standard. The certificate is most often issued by an independent external body.

Component. See Unit.

Configuration Item (CI). A configuration item is an aggregation of hardware and/or software and/or firmware that satisfies an end use function and is designated by the customer for separate configuration management.

Contractor. An individual, partnership, company, corporation, association, or other service having a contract with the customer for the design, development, manufacture, maintenance, modification, or supply of items under the terms of a government contract. For the purposes of this specification, prime contractor is synonymous with the term contractor.

Control Chart. A graphical representation of data used to detect, identify, analyze, and eliminate unacceptable variation in a given characteristic, process, or product. Computer software programs may be used for this purpose without a need to display the control chart itself. Commonly used control charts display variables or attributes process data with associated control limits. Control charts facilitate analysis of the process yield leading to potential changes in processes, methods, machines, and requirements documentation; evaluation of defect distributions to focus on significant causes of nonconformance; analysis to distinguish between chance and assignable causes of variation; and monitoring of the effectiveness of corrective action.

Control Limits. Criteria that establish maximum variation beyond which an out of control action plan (OCAP) must be invoked to investigate excessive variation, and when feasible, correct the cause(s) of nonconformance. An OCAP may also be invoked when abnormal patterns of variation occur without any individual data exceeding the control limits. Control limits are developed using standard statistical methods or other approved techniques and are based on documented process history. They are established to assist in fulfilling the contractor's responsibility for submitting a conforming item, reviewing the results of corrective actions, and reducing nonconformance levels.

Corrective Action. Changes to processes, work instructions, workmanship practices, training, inspections, tests, procedures, specifications, drawings, tools, equipment, facilities, resources, or material that eliminate the recurrence of nonconformances.

Corrective Action Board (CAB). A board consisting of management representatives of appropriate contractor organizations with the level of responsibility and authority necessary to ensure the prevention of nonconformances, to manage quality improvement efforts as appropriate, to assess and manage nonconformance cost elimination, to ensure that causes of nonconformances are identified, and that corrective actions are implemented throughout the contractor's organization.

Critical Item or Component. A flight item whose failure in operation or likelihood of failure would seriously endanger the safety of personnel or seriously degrade the mission or result in mission failure. Critical items need to be identified and managed. Critical items may be defined in the prime contractor's contract or statement of work. Potential examples of critical item characteristics include the following: items that are single point failures, new items never before used or new designs, items involving complex or new technology, items which contribute significantly to the design reliability, items produced by suppliers with historically significant production problems, schedule critical items,

hardware involved with separation events, or items in short supply or long lead times or requiring special handling procedures.

Critical Supplier. A critical supplier produces a critical item and is managed with a critical item control plan to help ensure success. Critical suppliers may meet the definition of involving excessive risk as defined in the contractor's directive documents or contract (such as a critical item control plan).

Data Package. A collection of artifacts as required by this standard or contract.

Directive Documents. Documentation which includes the contractor's processes and procedures. This is also known as command media.

Failure Review Board (FRB). See comment at end of Material Review Board.

Field Location. An offsite assignment for a contractor employee that may be of temporary or permanent duration.

Functional Configuration Audit (FCA). The formal examination of functional characteristics of a configuration item, prior to acceptance, to verify that the item has achieved the requirements specified in its functional and allocated configuration documentation.

Hardware Acceptance Review (HAR). A HAR is a formal buy-off review with the objective of verifying that hardware has been manufactured and tested in accordance with current design and test documentation prior to customer acceptance via a DD-250 and/or delivery to the next highest level assembly or to the launch site.

Item. A non-specific term used to denote any product, including systems, materials, parts, subassemblies, sets accessories etc. (Source: MIL-STD-280. *Definitions of Item Levels, Item Exchangeability, Models, and Related Topics*)

Major Supplier. Major suppliers produce items that, should they fail, could have a major effect on program costs and schedules. They should be managed and overseen in a similar manner as subcontractors.

Material Review Board (MRB). A board consisting of representatives of contractor departments necessary to review, evaluate, and determine or recommend disposition of nonconforming material referred to it. This board may also be called a Manufacturing Review Board. Failure Review Boards (FRBs) are essentially the same as MRBs but address test issues.

Minor Nonconformance. A nonconformance that does not adversely affect any of the following:

a. Health or safety. Performance
b. Interchangeability, reliability, or maintainability
c. Effective use or operation
d. Weight or appearance (when a factor)
e. Significant program cost
f. Contractual requirements

Note: Multiple minor nonconformances, when considered collectively, may raise the category to a major/critical nonconformance.

Major/Critical Nonconformances. A nonconformance other than minor that cannot be completely eliminated by rework or reduced to a minor nonconformance by repair.

Note: Where a classification of defects exists, minor defects are minor nonconformances. Major and critical defects which cannot be completely eliminated by rework or reduced to a minor nonconformance by repair are major/critical nonconformances.

Nonconformance. The failure of a unit or product to conform to specified requirements. The failure of a characteristic to conform to the requirements specified in the contract, drawings, specifications, or other approved product description.

Nonconforming Material. Any item, part, supply, or product containing one or more nonconformances. (Source: MIL-STD-1520C, *Corrective Action and Disposition system for Nonconforming Material*)

Occurrence. The first time a nonconformance is detected on a specific characteristic of a part or process. All nonconformances attributed to the same cause and identified before the assignment of corrective action are also considered occurrences.

Physical Configuration Audit (PCA). The formal examination of the "as-built" configuration of a configuration item against its technical documentation to establish or verify the configuration item's product baseline.

Pre-award Survey. An evaluation of a prospective supplier's capability to perform under the terms of a proposed contract. The approach ranges from simply completing a questionnaire, to visiting the supplier's facility, to conducting a complete audit.

Preliminary Review (PR). An evaluation by contractor-appointed quality personnel, assisted by other personnel as required, to determine the disposition of nonconforming material after its initial discovery and prior to referral to the MRB. PR may result in an authorized disposition of the nonconforming material without referral to the MRB for final disposition.

Preventive Action. Changes to processes, work instructions, workmanship practices, training, inspections, tests, procedures, specifications, drawings, tools, equipment, facilities, resources, or material that prevent potential nonconformances from occurring.

Product Assurance (PA). The function devoted to the study, planning, and implementation of activities intended to ensure that the design, controls, methods, and techniques in a program result in a satisfactory level of quality in a product. PA participates in all phases of a program: proposal, design, fabrication, supplier issues, test, deployment, and operation. It has the responsibility for assuring the customer that program specific requirements are flowed to the necessary parties and implemented. It therefore acts as a customer program point of contact for quality issues. For large programs, PA will support the program office. (Adapted from ISO 14300-2:2011, *Space Systems – Program Management – Part 2: Product Assurance*).

Product Discipline. Overall factory process control using a defined manufacturing flow, work documentation, travelers, referenced drawings and specifications.

Quality Assurance. Quality assurance (QA) is the planned and systemic activities implemented in a quality system so that the quality requirements for a product or service are fulfilled. QA focuses on the entire quality system including suppliers and ultimate consumers of the product or service. It includes all activities designed to produce products and services of appropriate quality. QA begins before a product is made or before a project is even started. Another way to look at it is that QA makes sure you are doing the right things, the right way. (Source: *Defense Manufacturing Management Guide for Program Managers*).

Quality Control. Quality Control (QC) refers to the activities used during the production of a product that are designed to verify that the product meets the customer's requirement. QC focuses on the process of producing the product or service with the intent of eliminating problems that might result in defects. QC begins as the product is being produced. Another way to look at it is that QC makes sure that the results of what you have produced meet your specifications. (Source: *Defense Manufacturing Management Guide for Program Managers*)

Quality Improvement Project (QIP). An activity chartered and monitored by the CAB (or other contractor group senior to the CAB) to investigate technology, methods, and procedures, which is aimed at finding more efficient and effective means of carrying out contractual responsibilities with the objective of enhancing quality and productivity.

Quality Management. Quality management includes all the functions involved in the determination and achievement of quality. This includes, but is not limited to, QA, QC, and PA. (Source: adapted from the *Defense Manufacturing Management Guide for Program Managers*).

Quality Program Plan (QPP). The document that defines the organization and approach to assuring adequate quality control for the program.

Recurrence. A repeat of a nonconformance after assignment of corrective action. (Source: MIL-STD-1520C, *Corrective Action and Disposition System for Nonconforming Material*)

Redundant Inspection/Test. Any verification of a quality characteristic performed by a higher-tiered supplier or contractor when the sub-tiered suppliers have properly verified that quality characteristic.

Repair. A procedure that reduces but not completely eliminates a nonconformance and which has been reviewed and concurred in by the MRB and approved for use by the customer.

Rework. A procedure applied to a nonconformance that will completely eliminate it and result in a characteristic that conforms completely to the drawings, specifications, or contract requirements. (Source: MIL-STD-1520C, *Corrective Action and Disposition System for Nonconforming Material*)

Scrap. Nonconforming material that is not usable for its intended purpose and which cannot be economically reworked or cannot be repaired in a manner acceptable to the contractor and/or customer.

Special Process. A special process has an output which cannot be effectively verified until after the product or service is delivered to the customer. A special process requires validation, that is, proving that the process is capable of producing the intended results by providing objective evidence.

Examples of special processes include welding, mold making, heat treating, plating, and wire crimping.

Standard Repair Procedure (SRP). A documented technique for repair of a type of nonconformance which has been demonstrated to be an adequate and cost-effective method when properly applied. SRPs are developed by the contractor, reviewed and concurred by the MRB, and approved by the customer for recurrent use under defined conditions. Defined conditions include an expiration date or a finite limit on the number of applications, or both.

Statistical Process Control (SPC). A methodology used to measure the average value and variability of any given characteristic within a contractor area, department, part, or process, including but not limited to, machine shop, bonding process, heat treat, and assembly. SPC techniques include control charts and control limits. Properly implemented, SPC offers the ability to improve manufacturing yield and lower production, inspection, and nonconformance costs.

Subcontractor. An organization that furnishes supplies or services under a prime contract. Purchases are made using subcontracts which are usually formal legal documents, which may include bonus and penalty clauses for exceeding or falling short of specifications. The subcontract has a statement of work (SOW) and is used for the purchase of complex items by the prime contractor.

Successive Inspection. The operator at the next step of the process inspects the product from the previous step of the process.

Supplier. The terms supplier, vendor, or seller are considered to be synonymous for the purpose of this standard. Purchases are made using purchase orders which include quality clauses and other specific requirements. Contractors normally set performance goals for their suppliers, such as on-time delivery and quality and periodically rate suppliers for acceptability. (See also critical and major supplier.)

Supplier Survey. The activity which determines the capability of the supplier to produce the desire product or service. A survey may range from a formal audit to simply a form completed by the supplier stating capabilities. For suppliers producing unique or complex components, a visit to the supplier is often justified.

Unit. An assembly or any combination of parts, subassemblies, and assemblies mounted together, normally capable of independent operation in a variety of situations. (Examples: deployment mechanism, gyro, electronic power supply, radio receiver.) This term replaces the term “component.” A unit should not be confused with a software unit.

Note: the size of an item is a consideration in some cases. An Application Specific Integrated Circuit (ASIC) which replaces a unit having several discrete circuit boards may be considered a part in as much as it is not normally subject to disassembly. (Source: adapted from MIL-STD-280A, *Definitions of Item Levels, Item Exchangeability, Models, and Related Terms*)

Use-As-Is. A disposition of material with one or more minor nonconformances determined to be usable for its intended purpose in its existing condition.

Virtual Audit. An audit conducted electronically with a reduced physical presence. Virtual audits involve mainly the review and discussion of paper documentation using a teleconference. An on-site audit team of one or two persons may still be employed during the virtual audit to conduct physical inspections of issues that arise during the virtual audit.

Work Instructions. The set of documents which detail how hardware is assembled or tested. Work instructions may include references to specifications or requirements, including workmanship standards.

4. Quality Management System

4.1 General

The QMS for space and launch vehicles shall be augmented by the requirements of this standard.

4.2 Contractor's Written Procedures

The requirements of this standard shall be implemented on a program specific basis by the contractor through the preparation, publication, and maintenance of detailed written procedures. The contractor shall identify personnel appointed to have preliminary review authority and those to act in material review and corrective action activities such as the material review board or corrective action board respectively and shall indicate in the procedures the scope or extent of their authority.

4.2.1 Quality Program Plan (QPP)

The contractor shall describe in a QPP the approach for managing and implementing the quality requirements of this standard. If a QPP is requested as a deliverable data item, reference Attachment 1, quality program plan, data item description. Software quality is an important discipline that shall be covered by a separate plan (see software quality plan below).

The QPP often addresses design reviews, fabrication, audits (internal and external), failure reporting, and the corrective action system. It usually will address the approach for the control of parts, materials, processes, reliability, software, supplier control, quality, test, and delivery. Depending on the program it may also identify launch site activities as well as integrated ground control activities. The quality program plan is a top level document intended to describe how necessary functions will be organized and activities accomplished. Rarely does it involve an in-depth treatment of any one topic.

4.2.2 Software Quality Plan

For deliverable software the contractor's approach to the program's software quality requirements shall comply with a customer approved software quality plan. For contractor developed non-deliverable software used to manufacture or test deliverable hardware or software, the contractor shall implement a disciplined management system for the validation and maintenance of such non-deliverable software. The software quality program approach shall be managed as a part of, and be consistent with, the general requirements for the overall quality program plan. For specifics on this requirement, see TR-RS-2015-00012 *Software Development Standard for Mission Critical Systems.*

4.2.3 Program Quality Approach at Field Locations

Controls over work performed at field locations shall be planned and executed with the same level of discipline as work performed at the representatives' home location.

4.3 Monitoring of Requirements

4.3.1 Tracking Requirements

All program policies and procedures addressing quality shall be readily available to all affected contractor personnel. The contractor shall verify that all requirements of this standard are met by their quality management system. Tailoring of this standard is permitted, as long as deviations are documented and recorded in the contract.

4.3.2 Program Specific Requirements

The contractor shall develop a method to assure that quality assurance requirements specific to and imposed by the contract are tracked and satisfied. The method shall allow personnel to easily distinguish unique program quality assurance requirements from those of other programs.

4.3.3 Supplier Requirements

The contractor shall develop a method to assure requirements imposed by the configuration item (CI) specification(s) and the contract, as well as the CI being procured for the program, are tracked and met. The method shall be used in the review of procurement documentation to provide a consistent and effective application of program requirements relating to quality.

Implementation: To ensure that all quality requirements will be met, a common practice is to complete a requirements matrix which cross-references each paragraph of this standard with the quality requirements paragraphs in the contractor's policy and procedure documents, quality manual, and /or quality assurance plan. In addition, the matrix tracks contract specific requirements. The matrix is then used to ensure contract specific requirements are also met by each supplier.

4.4 Records

The contractor shall maintain a system for the collection and analysis of quality records resulting from the procurement, manufacturing, inspection, test, and use of articles, parts, and materials to produce the CI. Quality information shall be promptly disseminated to all concerned areas within the contractor's organization and to involved suppliers when problems or deficiencies are detected.

4.4.1 Documentation Requirements

The contractor shall establish a system for identification, traceability, and control of parts, materials, and assemblies from acquisition (purchasing) including special screening tests through manufacturing/production, assembly, and delivery. Flight units and specified critical items shall require individual identification and data retrieval, which includes design and manufacturing documentation traceable to their origin. This will provide the capability of tracing backward from fabricated hardware to the records or material from which the item, part, and material originated. Identification and retrieval shall be required through all levels of higher assembly. The system shall provide for identification and suitable marking of flight hardware.

4.4.2 Recording and Retrieval of Records

Provisions shall be made to record and retrieve information relating to the specific tests performed, test results, and processes on each lot of parts and materials including pre-screening or lot retests. When serialization is required, controls shall be established to ensure that identification serial numbers are assigned in a consecutive manner. Records shall indicate applicable part or material identity and associated detailed information.

4.4.3 Unit Level Data Packages

The contractor shall establish and maintain data packages for all units including all subcontracted units. (See implementation after clause 4.4.4.) The packages shall contain the complete chronological history from the beginning of unit build through final acceptance of the component. A fully integrated data package shall be available for customer review. It is required for each serialized unit of the flight

as well as qualification items, including spares. The package shall include as a minimum the following:

a. Complete unit build history starting at the lowest level of assembly

b. Identification of manufacturing instructions and processes used to build the unit

c. Complete build inspection and test records, including physical and functional discrepancies, their resolution, and repair and rework history

d. Material review board (MRB) actions, waivers and deviations, where applicable

e. Test history including environmental test exposure and related measurements, where applicable, trend data across the testing, accumulative trend data across family of units, failures and anomalies during unit test, resolution, and retest

f. Identification of associated test equipment and test software, where applicable along with critical test calibration results

g. Associated failure reports including failure analyses leading to identification of root cause, disposition, and corrective action

h. Identification of any unverified failure (a failure in which the root cause has not been clearly established) and analysis of worst-case repair if applicable. If, in subsequent testing, the failure never occurs again, rationale should be given for ascribing the failure to a cause other than flight hardware

i. Cumulative operating time or number of cycles and accumulative vibration and temperature exposures when applicable

j. Unit as-built configuration description including a configuration status accounting for the as-built versus as-designed configuration at the time of unit delivery

k. Records reflecting traceability of parts, materials, and subassemblies installed

l. Storage history

m. History of the unit from the time it is first integrated into a higher assembly, to include: initial installation date; removal date(s); reason for removal; discrepancy and failure history; and traceability references to all inspection, discrepancy, failure, rework, repair, and retest paperwork

n. Product photographs when specified

4.4.4 Vehicle Level Data Packages

The contractor shall establish and maintain a data package for each serial numbered vehicle. (See implementation at end of section.) An end item data package shall be delivered in accordance with the contract data requirements list (CDRL). The data package shall contain the complete integration and test history starting with subsystem integration and continuing through final acceptance test of the vehicle. The data package contents shall be available for review by the customer. Each package shall contain, at a minimum, the following principal data:

a. Build log

b. Inspection history

c. Chronological test history including all out-of-sequence operations

d. Configuration status accounting of the as-built versus the as-designed configuration

e. A record of failure, anomalies, variations, and deviations identified during vehicle level or system level test (including any retest) and their resolution including root cause determination and corrective action

f. Identification of any unverified failure (a failure in which the root cause has not been clearly established) and analysis of worst-case repair, if applicable. If, in subsequent testing, the failure never occurs again, rationale should be given for ascribing the failure to a cause other than flight hardware

g. Test history including environmental test exposure and related measurements, trend data across the testing, and accumulative trend data across family of vehicles, where applicable

h. Applicable waivers, deviations, and vehicle level MRB actions

i. Component/equipment time recorded, status of on-time, or number of cycles for cycle sensitive items

j. Modification history including a list and description on any modification approved and scheduled for retrofit

k. Installation history of traceable components including removal and replacement history

l. Connector mate/demate logs

Implementation: In recent years, contractors and suppliers have moved toward storing on computer systems all quality records associated with unit and vehicle level data packages. In this approach, the data package is usually not a collocated set of data, but rather consists of a series of separate links to the relevant data. If this approach is used, the contractor should ensure that the data is still retrievable, consistent with program data retention requirements, under any future data system updates, changes in software, or system failures. Furthermore, the contractor makes the data accessible to any customer representative performing a review or audit of the data. In addition, the contractor should maintain a map or instruction set as to where the data is stored and how it can be accessed. This requirement assures that when the program is at its end, a person can locate the necessary data without special knowledge of the program or how the data were organized.

4.4.5 Nonconforming Material Documentation

The contractor system shall maintain records of all nonconforming material, dispositions, assignable causes, corrective actions, and effectiveness of corrective actions. These records shall be organized to permit efficient retrieval for summarization, knowledge of previous dispositions, and corrective action monitoring. The contractor shall ensure that documentation of nonconformances includes the following:

a. Identification name or number which is traceable to the contract number

b. Initiator of the document

c. Date of the initiation

d. Identification of the document for traceability purposes

e. Specific identification (e. g., part number, name, national stock number) of the nonconforming material

f. Quantity of items involved

g. Number of occurrences

h. The place in the manufacturing process where the nonconformance was detected

i. A detailed description of the nonconformance

j. Identification of the affected specification, drawing, or other document

k. A description of the cause(s)

l. Disposition of the nonconforming item (return to supplier, rework, use of an SRP, scrap, or refer to MRB)

m. Identification of personnel responsible for making the disposition decision

5. Management Responsibility

5.1 Quality Management

The contractor shall make functional assignments to implement each element of the program's quality requirements. Personnel performing quality functions shall have well-defined responsibility and authority. Personnel performing quality functions shall also have the organizational freedom to assess problems and to recommend and affect solutions.

5.1.1 Quality Assurance

The quality assurance (QA) organization and function shall be independent of organizations responsible for producing contractually required products and services.

5.1.2 Quality Control

The quality control (QC) organization often is a part of the QA organization and thus independent of production. If the contractor determines greater efficiencies may be achieved by having QC report to production, that arrangement shall be demonstrated through the use of metrics and QA audits that product quality and QC independence is not compromised by this reporting structure. Furthermore, a documented procedure shall be used to allow QC to alert QA to quality problems.

Implementation: A contractor has decided to restructure the quality organization for greater overall efficiency. QC managers will report in parallel with manufacturing managers to a common manufacturing director. This change removes the daily manufacturing needs to coordinate inspection support with a separate quality management organization. It also may enable quality management to devote more resources to QA for improvement of audits and factory quality metrics. However, QA is concerned that manufacturing could, with time, exert an unhealthy influence over inspection. To satisfy the requirements of this standard, QA institutes a quarterly meeting between the QC managers and the QA lead to discuss any problems or concerns in the factory. Although QA has confidence in the current manufacturing director, they realize that changes brought about by schedule or cost pressures can have an adverse effect on quality. Even personnel changes can influence the performance of QC. To support this standard, they consider four pilot metrics with potential adverse trends indicated in parentheses: changes in the inspector to technician ratio (lower), elimination of inspection points (lower), nonconformities that were missed by inspection (higher), and the overall nonconformities trend in general (higher). QA implements the first metric. To down select from the remaining metrics, QA realizes that the data must be normalized and begins to monitor nonconformities per thousand operator hours every month. They back test the metric producing data points for the last two years and decide that a control chart can be used to monitor the data. After six months of monitoring, QA notices a non-random pattern which may indicate a special cause of variation. They proceed through a previously developed out of control action plan and discover the pattern is related to an artifact of data collection, not organizational change. They continue to monitor the metric and discuss their findings with their government customer for evaluation and suggestions for improvement.

5.1.3 Product Assurance (PA)

The contractor shall designate one individual responsible for directing and managing the product assurance function. Depending on the magnitude of programs and customer needs, this individual may manage many people (typically program quality engineers) who shall report regularly to higher management, including their assigned program managers as well as the quality management

representative as defined in AS9100C, on the status and adequacy of the overall program's quality requirements.

5.1.4 Documenting Responsibility

The contractor shall document the assignment of management responsibility and authority for each task of the program's approach to quality requirements. Documentation shall include the following:

a. Organization charts depicting managerial levels, lines of communications, and personnel assignments
b. Identification of the level of management having authority to review the status of the program's overall quality approach and for assuring the adequacy of corrective actions including those between departments and programs
c. Narrative statements describing the responsibility of each element of the contractor's organization (e.g., procurement, engineering, reliability, fabrication, test, safety, and quality assurance), which implement the quality tasks on the program
d. The approach to quality management and surveillance of subcontractors and major suppliers
e. Analysis of customer requirements to ensure they are met

5.2 Management Reviews

PA shall conduct regular reviews for senior program management on the quality status of the program, including the following:

- Audit results
- Customer feedback
- Failure/discrepancy data
- Process trend data
- Status of improvement, preventive, and corrective actions
- Scrap/rework/repair status
- Costs and quality status for in-plant, intra-contractor operations, subcontractors, and major suppliers
- Follow-up actions from previous reviews
- recent changes that could affect the quality management system

Records shall be kept of these reviews and their recommendations. The frequency of these reviews shall be specified in the contractor's Quality Program Plan.

6. Resource Management

6.1 Skill Requirements

During initial quality planning, the contractor shall identify and provide for the physical requirements and skills needed to accomplish critical processing and manufacturing operations. Requirements for manufacturing and inspection personnel shall include the levels of visual acuity and color perception needed to perform operational functions.

6.2 Training Program

The contractor shall maintain a training program to provide adequate skill levels, including formal and on-the-job training. There shall be sufficient formal training to ensure proficiency of persons performing complex or critical operations. The training program shall include indoctrination regarding reliability and quality requirements of the product.

6.2.3 Training Records

The contractor shall maintain records of the training, testing, and certification status of personnel. These records shall be accessible so that managers may expeditiously verify the status of each person.

Implementation: Managers know best the training requirements of personnel that work for them, whether they are the company's requirements (i.e., ethics, safety, security, etc.) or the specifics of the employee task (i.e., soldering, crane operation, welding, etc.). Managers then identify the specific training requirements for each employee. Best records management systems for training have five components.

- The first is a mechanism for the manager to identify the training required for each employee. This information is entered into a corporate training database.
- The second component is the corporate database which holds requirements and training or certifications recorded for each employee. This information is fed back to the employee in a timely fashion so that the employee can recertify or update training before certifications expire.
- The third component is a parallel reminder system to the manager, so that the manager is aware of any employee lapses in training.
- The fourth component is a lock out mechanism that prevents an employee from working on a program if he or she lacks the current training requirements for the task.
- The final component is a local records management conducted by the manager which records any on-the-job training (OJT). These records include who was trained, when the person was trained, and a copy of the material presented to each employee.

Weaknesses in the system can be identified by audits. Systems that divide training records, for instance using separate databases for corporate human resource type training and technical training, add an extra layer of complexity which may allow a violation to occur.

6.3 Shift Change Coordination

The contractor shall make provision for adequate exchange of information between shift changes so that production and test activity can proceed without interruption or delay. Exchange of information should include as applicable test results and status, test failures, production status, equipment status and environmental controls, preliminary and material review status, staffing levels such as the number of inspectors available, schedule changes, etc.) Normally this coordination is accomplished by overlapping the start and stop times of the two shifts involved.

7. Product Realization

7.1 Planned Reviews

Space programs require significant resources (time and money) to develop the correct approach and ultimately produce the required system. As expected the customer and contractors have developed a number of planned reviews that have proved to be important for assuring quality is maintained throughout the program.

7.1.1 Preliminary and Critical Design Reviews (PDR and CDR)

PDR and CDRs are discussed in more detail in the TR-RS-2009-00021 *Technical Reviews and Audits for Systems, Equipment, and Computer Software* and TR-RS-2013-00001 *Systems Engineering Requirements and Products*. The description of the QMS shall be included in these reviews as well as the quality metrics that will be used to manage the program. Quality representatives shall participate in the PDR and CDR.

7.1.2 Manufacturing Readiness Reviews (MRR)

Before commencing manufacture of a unit or other contractually designated configuration items at the contractor, subcontractor, or critical item supplier, the contractor shall conduct a MRR to ensure readiness to build a quality product. Representatives from the appropriate design, manufacturing, test, parts, material, processes, quality, and other responsible organizations shall participate as a minimum. The appropriate customer representatives shall be invited and allowed to participate. Topics covered shall include, but are not limited to the following:

a. drawing availability and acceptability
b. configuration status
c. producibility of parts and materials
d. adequacy of manufacturing processes/certifications
e. manufacturing planning
f. current manufacturing trend data
g. personnel experience and training/certifications
h. tooling
i. facilities
j. inspection points
k. test equipment availability and calibration status
l. corrective action status and manufacturing lessons learned from prior like hardware builds and schedule.

Implementation: An MRR may be conducted by coordinating a physical meeting between all designated parties. The advantage of this approach is a formal interaction between all subject matter experts (SME), even from different disciplines. The downside of this approach is the expense of organizing and documenting a meeting as well as the real possibility that all parties may not be able to simultaneously attend. However, with the advent of modern business systems, the MRR may be conducted virtually. The downside of this approach is that subject matter experts (SME) from different specialties may not interact. However, the virtual approach potentially allows SMEs to provide better documentation and more effectively reflect on issues. In the latter case, access to the business systems should be provided when participants lack the necessary permissions (e.g., customer representatives may lack permissions to use the contractor's business systems).

7.1.3 Test Readiness Reviews (TRR)

Before commencing testing of a unit or other contractually designated configuration item at the contractor, subcontractor, or critical supplier, the contractor shall conduct a TRR to ensure readiness to adequately test the unit or other configuration item. Representatives from the appropriate systems engineering, design, test, manufacturing, quality, and other responsible organizations shall participate as a minimum. The appropriate customer representatives shall be invited and allowed to participate. Topics covered shall include, but are not limited to:

a. test requirements
b. test planning
c. test procedure availability and adequacy
d. test set-up
e. configuration status
f. test software availability and adequacy
g. personnel experience and training
h. facilities
i. test equipment and calibration status
j. test lessons learned from prior like hardware testing, and schedule.

Also, open and closed anomalies or liens that affect qualification or acceptance testing shall be reviewed.

Implementation: A TRR may be completed as a physical meeting between all designated parties or completed as a virtual meeting. Advantages and disadvantages are similar to those listed for MRRs under clause 7.1.2. If a virtual meeting is used, access to the business systems should be provided when participants lack the necessary permissions.

7.2 Manufacturing and Test Planning

The contractor shall develop manufacturing, inspection, and test instructions for all segments of the manufacturing cycle, which shall include flow charts or other effective alternative methods of identifying all inspection and test points. The contractor's QA and/or PA organizations shall participate in the planning development and shall review and approve the instructions prior to release. Instructions shall include or reference engineering requirements, such as drawings, material

specifications, process specifications, and workmanship standards, to assure that necessary tests and inspections are effectively performed to verify that the product meets technical requirements. Test instructions shall identify the characteristics to be measured, the methods of measurement, and the point at which the test is to be performed. Any changes made to production processes, equipment and/or test equipment/tooling shall be documented. Results of such changes shall be assessed. The contractor shall address the following in developing the required manufacturing inspection and test instructions:

a. Sequence of all manufacturing, inspection and test points to assure continuity and effectiveness of all operations

b. Inspection and test performance at the optimum item indenture level to minimize repair or rework at higher indenture levels. All workmanship shall be inspected at least once and preferably twice before being covered up by subsequent operations. If a second inspection is employed, the inspection approach should not be an exact duplicate of the first inspection. For instance, it could be at a higher level or involve a different approach than the first. Successive inspection is also a suitable approach in lieu of one of the quality inspections.

c. Sufficient module level environmental testing and burn-in

d. Cleanliness/contamination control to include foreign object control

e. The adequacy of in-house handling and packaging, including provisions for protection of electrostatic discharge sensitive items

f. Availability and utilization of applicable drawings, specifications, and standards

g. Clearly defined acceptance or rejection criteria for each inspection or test

h. Special attention to monitor and document critical items and their characteristics

i. Visual aids for inspection and assembly personnel

j. Appropriate selection, application, use, and control of substances, chemicals, shop aids, clothing, and expendable materials specified and used in the manufacturing process (cleaning materials, adhesives, joining material, solvents, rags, etc.)

k. Test equipment, tooling, jigs, fixtures, and other fabrication equipment to be utilized

l. Insertion of appropriate mandatory inspection points for manufacturing and quality organizations

m. Inclusion of MRRs, TRRs, and hardware acceptance reviews for units and other configuration items

n. Provisions to record process data, e. g., start and stop times, temperatures, torque values, etc.

Implementation: Contractors may employ computerized systems which make available real time access to instructions and provide for electronic sign-off of operations. These systems may even check training records for employees performing tasks. If electronic work instruction systems are used, the contractor will verify that the system cannot be bypassed. For example, if data entry terminals are inconveniently accessed, the employee may make notes of several operations and then enter the data after the fact technically bypassing the intended real time use of the system.

7.3 Workmanship

The contractor shall develop methods to assure that workmanship is adequate to meet contract end item specified requirements.

7.3.1 Workmanship Standards

The contractor shall establish workmanship standards if the standards are not specified by contract or statement of work (SOW). These standards can be part of design specifications, drawings, work instructions or other readily available specifications and standards. These standards shall be derived from industry accepted workmanship standards and also be based on the contractor's manufacturing experience. All standards shall be aimed at delivering the highest quality and most reliable hardware to the customer possible within the constraints of the contract. All standards shall define specific detailed acceptance or rejection criteria.

7.3.2 Visual Aids

When visual aids are used to support manufacturing or inspections, the contractor shall identify, maintain, and control the samples, graphics, or visual aids that show acceptable workmanship to ensure continued usability and proper configuration.

7.4 Design, Manufacturing, and Test Quality Control

7.4.1 Drawings, Documents, and Changes

The contractor shall ensure that drawings, specifications, and technical documents and changes thereto contain adequate requirements and criteria for determining and controlling the quality of all items purchased or produced by the contractor. A procedure shall be established to identify, analyze, and report engineering documentation errors. Corrective measures shall be initiated when analysis indicates errors are beyond the predetermined acceptable limits.

7.4.1.1 Control of Drawing, Documents, and Changes

If not covered by contract or tailoring, the contractor and his subcontractors and suppliers shall conform to TR-RS-2006-00002 *Configuration Management*.

7.4.2 Design Reviews

The contractor's internal design review program shall include participation of quality assurance, manufacturing, engineering specialty organizations, and others that are users of design documentation. This should consist of review and approval of all design disclosure technical documentation, and changes thereto, prior to formal document release.

The review shall provide for independent evaluation by personnel knowledgeable and experienced in the quality assurance and control aspects of the manufacturing process. For all new and modified designs, at the unit level and above the appropriate customer representatives shall be notified of the design reviews and allowed to participate. At a minimum, the following characteristics shall be assessed:

a. Features that enhance or diminish the practicality of inspection, measurement, and verification of conformance to design requirements, including acceptance requirements

b. Proven and demonstrated inspection and test techniques to verify the adequacy of the design. Appropriateness of inspection and test procedures as well as performance of personnel using the designated equipment is demonstrated to detect design flaws in representative samples

c. Effectiveness of test points

d. Identification of unnecessary and unrealistic design complexity as judged by inspectibility and manufacturability

e. Evaluation of the extent to which single point failure modes and mechanisms have been eliminated, or compensating features included

f. Features that enhance ease of manufacturing

g. Unique or new tooling requirements

h. Complete, clear, accurate, and unambiguous display of technical requirements in drawings, specifications, other engineering documentation, and process standards

i. Specification of nominal useful life, and identification of limited life items, and storage limits

j. Necessity and feasibility of special evaluation or inspection methods, including destructive and nondestructive evaluations

7.5 Hardware Acceptance Reviews (HAR)

Before integrating units or other configuration items into subsystems or systems at the contractor, subcontractor or other facility, the contractor shall conduct a HAR to ensure the quality and reliability of the hardware. The data package contents described below shall be available for review prior to and during the HAR.

Personnel assigned to perform a HAR should be familiar with the basic design, construction, and test of the spacecraft or launch vehicle hardware in addition to the particular subject matter associated with the unit(s) under review. While the conduct of HARs is often viewed as a QA function, composition of the review team may have a variety of disciplines including systems engineering, design, test, manufacturing, reliability, and Parts, Materials and Processes (PM&P). Customer participation in HARs is encouraged and should be recommended; however, customer participation is at their discretion.

The minimum data review shall include the following:

- Final inspection and acceptance test records showing unit acceptability
- Complete unit level nonconformance reports, MRB actions, failure reports and test/failure review board actions, and associated analyses (e.g., overstress analyses, summary level rework and repair)
- Complete test history records with environments seen and sequence of testing
- Identification of any unverified failures encountered with an associated risk analysis including analysis of worst case repairs, as applicable, as well as out-of-family test results
- Cumulative unit operating time/cycles, vibration, and temperature exposure logs and data

- Unit as-built versus as-designed configuration records with appropriate reconciliation or any deltas
- All waivers and deviations requested and approved for the unit
- History of the unit from the time it is first integrated into its next higher assembly including installation and removal data
- Storage environment and length of storage if stored for longer than six months

A more comprehensive HAR may include the following:

- Complete unit build history starting at the lowest level of assembly
- Identification of manufacturing instructions and processes used to build the unit
- Complete chronological build, inspection, and test records, including physical and functional discrepancies, their resolution, and detailed repair and rework history
- Analysis of trend data across the unit being tested and comparison with other like units
- Complete identification of associated test equipment and test software, where applicable, along with critical calibration results
- Bill of materials or component/part trace records reflecting traceability of parts, materials, and subassemblies installed
- Complete storage history
- Product photographs and drawings

7.6 Control of Purchases

7.6.1 General Requirements

The contractor shall institute a program to control purchases of flight hardware and to flow down the requirements of the contract to suppliers and subcontractors. The program shall include a process to preclude the use of counterfeit parts throughout the supply chain.

7.6.2 Intra-contractor Work Authorization

All intra-contractor work transferred between departments, divisions, or other organizational segments shall be controlled to assure compliance with the technical quality requirements of the contract in the same manner as if they were a supplier or subcontractor.

7.6.3 Selection of Supplier

7.6.3.1 Determining the Supplier's Capability

The contractor's quality approach to meet program requirements shall include procedures for the determining, prior to issuance of the purchase document, the capability of the prospective suppliers of flight hardware, whether existing or new, to produce the products in accordance within contractual requirements. Each non-approved supplier shall be surveyed by the contractor in the 18 months prior to the start of the contract. For existing suppliers of complex components, unless the supplier has been producing the desired product or service during the past 18 months, the contractor shall perform a pre-award quality survey as described in 7.6.3.2 below.

7.6.3.2 Pre-award Survey of Prospective Suppliers

When the contractor performs a pre-award survey of the supplier's facility, the results shall be documented, available for review, and serve as a basis for required corrective action upon receipt of the subcontract.

7.6.3.2.1 Survey Elements

The following factors, appropriate to the products or services to be furnished, shall be considered for evaluation during the survey:

a. Management organization and approach. Significant changes in management
b. Inspection planning, controls, capability, and management
c. Product/commodity visibility and defect prevention program
d. Product/commodity performance analysis
e. Past experience with the type of product or service to be supplied
f. Configuration management system
g. Procedural control of hardware/software design and development documents and associated changes
h. Control of nonconforming products
i. Corrective action/continuous improvement program
j. Product technology and processing controls
k. Personnel availability/qualifications/certification. Significant changes in personnel
l. Review/audit capabilities
m. Calibration capability and resources
n. Relevant industry alerts associated with the products or services to be provided by the supplier

7.6.3.2.2 Hardware Specific

The following factors apply only to hardware products and shall be considered for evaluation during the survey:

a. Manufacturing facilities. Significant changes in facilities such as a move, merger, or acquisition
b. Capability/condition of manufacturing equipment
c. Control and maintenance of inspection equipment and production tools used as a medium of inspection
d. Material storage and handling
e. Control of nondestructive testing and special processes
f. Control of destructive testing

7.6.3.2.3 Software Specific

Software survey elements are discussed in more detail in TR-RS-2015-00012 *Software Development Standard for Mission Critical Systems*. The following factors apply to software/firmware products to the extent that they are specified in the software quality assurance program plan and shall be considered for evaluation during the survey:

a. Software media controls
b. Software development standards and procedures
c. Existing software development, test and support tools, methods and measurements
d. Software validation/verification methodologies
e. Software library controls
f. Independence and qualification of evaluators

7.6.4 Supplier Rating

7.6.4.1 Periodic Audit of Suppliers

Each active supplier of flight hardware shall be subjected to a periodic review/audit of their quality management system. The type of review and frequency shall be defined in the contractor's procedures. The purpose of the reviews/audits will be to determine the continued capability of the supplier to control the quality of the products or services specified by the contract. Should there be any significant changes at a supplier's facility (e.g., facility moves, top level management change, etc.) or any evidence of poor quality, there should be an immediate contractor audit. The contractor shall notify the customer representative of the audit schedule for suppliers of major/critical items and any changes to those schedules.

The contractor shall strive to make use of relevant audits performed by other qualified organizations to satisfy the periodic review/audit requirement. However, when there is a technical concern, the contractor shall use program personnel with the necessary process specialists to investigate potential shortcomings of the supplier.

Implementation: It is recognized that audits are an expense and logistical challenge for suppliers, particularly when the supplier is dealing with multiple contractors. Therefore, the contractor is encouraged to use the results of other qualified organizations to satisfy the requirement. Typical audit results that may be used to satisfy the requirement are the following: registrar audits, supplier internal audits, and audits performed by different programs. The contractor may explore teaming with the supplier's internal audit effort to perform a joint audit to reduce the audit burden on the supplier.

7.6.4.1.1 Contractor Auditing Approach

Periodic audits addressing the quality management system shall be conducted in a structured manner.

7.6.4.1.1.1 Audit Team

The contractor shall establish auditor training and experience requirements for all members of the audit team. This training shall consist of a certification process to address technical audits as well as quality management system audits. When a lead auditor conducts a quality management system audit,

the lead auditor shall have completed a lead auditor course addressing the current standard of AS9100. An American Society for Quality (ASQ) Certified Auditor course completion is also suggested.

7.6.4.1.1.2 Checklist

A checklist shall be prepared to explain the scope and detail of the proposed audit. This checklist shall be shared with the supplier at least one week in advance of the audit with one exception: if the audit is an unannounced audit because of a technical issue, the checklist does not need to be shared with the supplier.

7.6.4.1.1.3 Evaluation by Management

Contractor supplier audit team performance shall be evaluated by management as defined in the contractor's procedures. The evaluation shall be used to determine if the auditors are qualified to participate in future audits. If auditors are no longer considered qualified, they shall receive additional training and mentoring before continuing the audit activity.

Implementation: Audit team performance should be evaluated more than solely by completion of the audit. Possible ways to evaluate auditors would be performance reports by the lead auditor or evaluation of the audit team by the supplier. The lead auditor may be evaluated by the quality and timeliness of the final report as well as evaluation by participating auditors or supplier evaluation.

7.6.4.1.1.4 Supplier Requirements

The supplier shall prepare an introduction to their quality management system and provide this to the contractor or major subcontractor prior to the visit so that the audit team may use this knowledge during the course of the audit. Examples of topics to be provided are the paper work systems, data bases, and contact personnel.

Implementation: Suppliers may consider sharing their results of registrar audit reports or audit reports from other programs of the same contractor or major subcontractor. The purpose of the sharing would be to eliminate duplication of audits if the contractor or major subcontractor plans to audit a process that has recently been audited by another team.

7.6.4.1.1.5 Virtual Audits

The contractor should consider the use of virtual audits to reduce costs when all supplier data to be reviewed is stored electronically. If a virtual audit is used, the contractor may send one or two auditors to be on site while the virtual audit is conducted so that a physical examination of the facility and product may still be made.

7.6.4.2 Supplier Rating System

A supplier rating system shall be devised by the contractor and described in written procedures. Each supplier shall be rated for quality of performance for each type of commodity/product being purchased. The system shall consider applicable inspection and test results when available from sources such as field personnel, as well as receiving inspection, and subsequent supplier responsible line rejects. The system shall yield the necessary basic data to provide visibility of supplier quality performance and trends. Ratings shall be available to suppliers and the system shall allow suppliers to offer objective evidence on their behalf to counter mistakes or misinterpretations of data that form the

basis of the rating. These data shall be periodically updated to reflect current supplier ratings and shall be used by purchasing personnel.

7.6.4.3 Rating

The supplier quality rating system shall provide adequate separation and identification of suppliers having a satisfactory rating from those having other than a satisfactory or acceptable rating. The rating shall be predicated on a history of quality performance. The supplier's quality rating should be given consideration equal to other performance indicators when selecting suppliers. The contractor's program shall describe to the supplier the precautions that shall be implemented when products are obtained from suppliers that are rated below the satisfactory level established in the contractor's rating system.

7.6.5 Purchasing Data

7.6.5.1 Responsibility

The contractor's supplier quality assurance program shall provide for a review of purchase documents to assure applicable quality requirements are included or referenced in the documentation for compliance by the supplier. The review shall be accomplished as early as possible in the procurement cycle to assure the incorporation of all requirements applicable to the specific purchase. The office responsible for this review shall be identified in the contractor's procedures.

7.6.5.2 Purchase Documentation Evaluation

Contractor evaluation of the purchase documents shall be accomplished under control of the quality organization to assure that an adequate description for the products to be provided, is included in the documentation.

7.6.5.2.1 All Purchases

The evaluation shall ensure instructions are included in all purchase documents for the following as appropriate:

a. Manufacturing requirements and controls
b. Inspection and testing
c. PM&P specifications/standards
d. Control of critical items
e. Special qualifications, approval, or certifications
f. Nondestructive and destructive test controls and record keeping
g. Control of hardware/computer software documentation and changes
h. Applicable product and process specifications
i. Reliability and maintainability
j. Safety factors
k. Packaging, handling, storage, and transportation (PHS&T)
l. Contractor source quality control inspections

m. Government industry data exchange program (GIDEP) participation
n. Age control/limited shelf life materials and products
o. Customer-furnished equipment
p. Contractor-furnished equipment
q. Data retention
r. Control of tool and test equipment
s. Nonconforming products
t. Reviews/audits
u. Identification of hardware and software deliverables (see TR-RS-2015-00012, *Software Development Standard for Mission Critical Systems*)
v. Variability reduction and/or SPC program
w. Trace requirements for hardware and software, including imbedded software

7.6.5.2.2 Software Purchases

Software requirements are discussed in more detail in TR-RS-2015-00012, *Software Development for Mission Critical Systems*. In addition to 7.6.5.2.1, the following applies to computer software products as appropriate and in accordance with the contractor's software quality assurance plan.

a. Software qualification/acceptance testing
b. Traceability between requirements and qualification/acceptance tests
c. Software development plan
d. Software quality program plan
e. Software specifications, standards, and programming conventions
f. Software media control

7.6.6 Contractor Control at Supplier's Facility

7.6.6.1 Control of Quality

The contractor shall be responsible for the following functions at supplier's facilities when the contractor stations personnel at the supplier because of the criticality or volume of the work:

a. Performing complete or sampling inspection of product characteristic
b. Assuring the adequacy of, and conformance to, the controls for special manufacturing processes
c. Assuring the adequacy of, and conformance to, the controls for inspection and test equipment
d. Verifying conformance to configuration management procedures for engineering drawings and computer software
e. Determining conformance to the supplier's established approach to quality requirements and their inspection system

f. Evaluating the methods for controlling nonconforming products and assuring the correction of the cause of nonconformance

g. Documenting results of evaluations and inspection performed

h. Indicating acceptability of products contained in each shipment, as applicable

i. Verify that qualification and acceptance tests are conducted to contractually specified procedures

j. Verifying compliance with contractual requirements to include timely notification to management when discrepancies/deficiencies are discovered

7.6.6.2 Control of Critical Items

When the contractor assigns permanent representatives at the supplier, the contractor shall maintain strict control of critical items and their processing regardless of manufacturing/process location. Purchase orders for critical items shall specify special PHS&T requirements. The following documentation shall be submitted to the contractor as part of the supplier's quality assurance plan or in a critical item control plan.

a. The methods and the type of critical processing to be used (subject to limitations imposed because of proprietary information)

b. The location within the processing cycle where inspections, audits, or walk throughs will take place

c. The attributes of the products, which will be inspected at each inspection point

7.6.6.3 Source Inspection

When a continued surveillance and/or an examination of customer-purchased product is required at the supplier's facility to ensure product integrity and conformance to specified requirements, the contractor shall provide resident or itinerant quality assurance representative(s) to perform this activity at the subcontractor's or vendor's facility. The requirement for a resident quality assurance representative shall be based on item design, mission criticality, subcontractor or supplier past performance, and other pertinent factors. The contractor shall have instructions for each resident or itinerant quality assurance representative to delineate their responsibility and authority at the subcontractor's or vendor's facility.

7.6.6.4 Unit Source Inspection

The contractor shall inspect all supplier supplied flight units and critical items at the supplier's facility unless otherwise specified in the contract.

7.6.7 Receiving Inspection

Products and services produced by outside sources for incorporation in the contract end item shall be subject to inspection/audit at time of receipt or if further processing is required for acceptance, at a time that does not violate the suppliers contractually specified warranty period. In either case the product shall be accepted prior to full integration of the product. A contractor, in lieu of receiving inspection/audit, may use objective quality evidence submitted by the supplier. The use of such evidence does not relieve the contractor of responsibility to meet all contract requirements. In addition to verifying that the products and services comply with requirements of the purchase

document, the products and services shall be verified against the latest applicable engineering changes or software specifications.

7.6.8 Delegation of Product Verification

When a contractor delegates product verification, the contractor shall conform to the requirements of AS9015 Supplier Self Verification Process Delegation Programs. The contractor reserves the right to conduct surveillance of the Supplier's facility to determine if the Supplier is compliant to AS9015. The contractor's receiving inspection reserves the right to re-inspect/retest the supplied products if deemed critical for system performance.

7.7 Manufacturing Control

7.7.1 Production Processing and Fabrication

7.7.1.1 Certification

7.7.1.1.1 Equipment Certification

The contractor shall establish a method to certify the qualification of the machines, equipment, and procedures used in complex, critical operations. Records shall be maintained of the qualifying tests performed and the results of such tests. Machines, equipment, and procedures shall be recertified as indicated by the results of quality trends or when major process changes are made (i.e., such items as material thickness, design, power source, capacity, voltage, density, swap out of equipment, move of facilities).

7.7.1.1.2 Personnel Certification

Contractor personnel performing or verifying complex or critical operations, and processes requiring a high degree of skill, shall be certified. Certification shall be based upon objective criteria, which include work experience, training, and testing. Certified personnel shall be provided evidence of certification, which shall specify the period of effectivity. When possible, personnel shall show proficiency on non-flight hardware which is representative of flight hardware before being allowed to work on flight hardware.

7.7.1.1.3 Personnel Recertification

When certification expires, personnel shall be recertified by testing or review of objective evidence of continued satisfactory performance. The contractor shall also recertify each individual whenever significant changes are made in processes, techniques, or skill parameters, or when physical relocation or interruption of the work period would result in degradation of quality. Whenever inspections, tests, or quality audits identify that individual manufacturing or inspection personnel need additional training, they shall be removed from the operation, provided with additional training, and demonstrate the required proficiency.

7.7.1.2 Cleanliness, Contamination, and Corrosion Control

The contractor shall review and identify the cleanliness, contamination, and corrosion control requirements derived from hardware specifications and ensure that procedures are developed to adequately protect the hardware during manufacturing, test, and PHS&T. Implementation of controls shall be monitored by quality assurance on a regular basis.

7.7.1.3 Control of Physical Environment

The contractor shall ensure through periodic audits or automatic control and warning systems that the physical environment (such as temperature, humidity, light, arrangement of work areas, or arrangement of machines and equipment) is controlled to preclude inadvertent damage to hardware and to prevent unsafe conditions in all work and storage areas.

7.7.1.4 Critical Item Quality Control Requirements

The contractor shall establish and maintain appropriate critical item control. Manufacturing shall include any special instructions in the appropriate planning shop folders, process plans, log books, and related documents controlling the manufacturing and movement applicable to in-house manufacturing. Components or materials selected for preferential treatment shall be conspicuously marked or tagged to alert personnel of special requirements unless such marking or the process of marking increases the likelihood of damage to the critical item. These items shall be segregated or have distinctively marked fixtures and locations in all stock rooms, holding and staging areas. Such items shall be regularly and systematically inspected for condition of expired time, cycle, or calendar life. Items with expired time, cycle, or calendar life shall be identified as nonconforming and properly dispositioned. Reviews of selected critical items shall be periodically conducted to verify the adequacy of work instructions and standards being used. If virtual marking is used, QA shall periodically review the effectiveness of electronic tagging rather than physical tagging.

7.7.1.4.1 Critical Item Verification

For each critical item, beginning at the start of assembly and at progressive levels of assembly and test, the contractor's quality organization shall verify that the contract, drawing, and specification requirements have been met on all such articles and materials, procured or produced. Anomalies, including trends, deviations from expected norms, and marginal conditions shall be identified. Detailed assessment of the quality of these items and their manufacture shall include:

a. Identification of potential design and layout problems which could cause latent defects or marginal performance

b. Verification that current manufacturing test methods and controls are producing repeatable products

c. A review of manufacturing problems, if any, which could be alleviated by additional (or revision of) engineering information

d. Verification that critical parameters are measured and verified by applicable test procedures

e. Decisions, dispositions, corrective actions, or recommendations are evaluated against appropriate criteria and previous history data

f. Anomalies noted or observed during review are analyzed, evaluated and dispositioned

g. Records are progressively reviewed and made part of the overall acceptance criteria

h. Identification and resolution of the differences between as-built and design documentation

i. Evaluation of failure and discrepancy reports to verify that reports identify underlying causes (symptoms or manifestations) and a summary of overstress and induced secondary failures

7.7.1.5 Electrostatic Discharge Control (ESD) Program

Procedures shall be established for the surveillance of the ESD control program. This shall include identification of items susceptible to electrostatic discharge and protective features to prevent such damage. As a minimum this should include:

a. Design criteria
b. Protected work areas and protective clothing
c. Process controls and workmanship standards
d. PHS&T
e. Training
f. Marking of documentation and hardware
g. Audit plan for certified ESD workstations

7.7.1.6 Nondestructive and Destructive Evaluation

Nondestructive evaluation methods, verification techniques (and attendant equipment and facilities), which are used to perform quantitative measurements, integrity analysis, and nondestructive testing, shall be controlled and integrated into the contractor's qualification, calibration, certification and standards procedures. Nondestructive evaluations for flight hardware CIs shall be performed by certified personnel (e.g., American Society for Nondestructive Testing (ASNT) certification). Destructive evaluation methods shall be controlled in a similar method to nondestructive evaluation methods.

7.7.2 Completed Item Inspection and Test

Prior to shipment or storage of a contract end item, the contractor shall review objective evidence generated during manufacturing and test of the item to assure that all work sequences have been satisfactorily completed and that all nonconformances have been resolved. The contractor shall maintain records and findings of final review.

7.8 Measuring and Testing Equipment

The contractor shall provide and maintain gauges and other measuring and testing devices necessary to assure that supplies conform to technical requirements. These devices shall be calibrated against certified measurement standards that are traceable to national standards at established periods to assure continued accuracy. The contractor shall assure that inspection and test equipment is adjusted, replaced or repaired before it becomes inaccurate. In addition, the contractor shall ensure the use of only subcontractor and vendor sources that have calibration systems that effectively control the accuracy of measuring and testing equipment. ANSI/NCSL Z540-3, *Requirements for the Calibration of Measuring and Test* is applicable to the contractor and all subcontractors.

Implementation: Older contracts may specify MIL-STD-45662 *Calibration Systems Requirements* and the contractor may not be able to justify the cost to re-negotiate these contracts. Note that this standard is cancelled. ISO17025 may be invoked for foreign suppliers, as they may not follow an American standard. ANSI/NCSL Z540.3 is replacing ANSI/NCSL Z540-1. Clause 7.8 should be tailored to agree with contractor practices, but the intent is to upgrade the measuring and testing equipment requirements to ANSI/NCSL Z540.3.

7.8.1 Production Tooling used as a Media of Inspection

The contractor shall control production tooling used as a media of inspection to ensure continued accuracy between periods of tool proofing.

7.8.2 Tooling Records

The contractor shall maintain records of tool proofing which provide for each tool the date last proofed, condition found, maintenance performed, and date of next proofing.

7.8.3 Tool Proofing Intervals

The contractor shall analyze the records of tool proofing in order to shorten intervals as required to ensure continued accuracy, or to lengthen intervals when the results of previous tool proofing provide definite indications that such action does not adversely affect the accuracy of the tool.

8. Measurement, Analysis, and Improvement

8.1 Disposition of Nonconformities

Several specific methods have been developed for addressing root cause and corrective action for space and launch vehicle nonconformities.

8.1.1 Preliminary Review (PR)

When material is initially found to be nonconforming, it shall be examined by contractor-appointed quality personnel, assisted by other contractor personnel as necessary. PR action does not negate the requirement for identification, documentation, and corrective action associated with non-conformances. It does recognize that some nonconformances do not warrant referral to material review (clause 8.1.2) and can be handled more economically at the location of initial detection. PR shall determine if the nonconformance requires the following:

a. Scrap the material because it is obviously unfit for use and cannot be economically reworked or repaired

b. Rework to eliminate the nonconformance

c. Return of the material to the supplier

d. Repair using approved standard repair procedures (SRPs) (see clause 8.1.3.2.1)

e. Meets none of the above criteria and shall be referred to material review

Implementation: Traditionally PR has been an informal meeting of at least the responsible engineer and the quality engineer. The PR is approved by personnel as designated in the contractor's procedures. However, more recently PR has been accomplished using a virtual meeting. If the latter is chosen, the business system provides for electronic signature of approved personnel for the PR disposition.

When the contractor's procedures specify and dispositions are adequately documented, PR may identify dispositions traditionally assigned to material review, such as clause 8.1.2 (d) (5-7). In this situation, the requirements of clause 8.1.2 often apply. When PR parties cannot agree on the disposition, the disposition is usually elevated to material review (clause 8.1.2).

8.1.2 Material Review (MR)

When nonconforming material is not disposed of by PR or addressed in sufficient depth by PR to determine the proper disposition as described in clause 8.1.1, it shall be elevated to material review. Contractor-appointed personnel shall conduct a material review, in a timely manner, of all remaining nonconforming material. The contractor shall ensure that the customer is kept informed of its investigation and deliberations on these potential dispositions so that the customer may act upon material review recommendations in a timely manner. When a material review board (MRB) is constituted, a designated customer representative shall be a member of any MRB. (See implementation comments below.) MR shall address the following:

a. Review and concur in all proposed use-as-is and repair dispositions and justifications

b. Review and concur in all proposed SRPs (see clause 8.1.3.2.1)

c. Ensure that a written engineering analysis accompanies proposed use-as-is and repair unless a SRP is applicable

d. Disposition of nonconforming material into one of the following categories:
    1. Scrap
    2. Rework
    3. Return to supplier
    4. Repair by an approved SRP
    5. Repair by other than an SRP
    6. Use-as-is
    7. Request a waiver from the contracting officer
e. Review hardware rework and repair histories to ensure that hardware is still fit for use

Implementation: Traditionally MR has been performed by a formalized MRB which meets on a periodic basis. A MRB is chaired by a representative of the contractor's quality organization and may include, as required, personnel representing other contractor technical functions necessary to determine appropriate disposition of nonconforming material. As a minimum, the MRB will include the chairman and a representative of the contractor's engineering organization responsible for product design.

MRB members may call upon other contractor personnel and customer representatives for technical advice. If warranted by the volume of nonconforming material or the diversity of work operations, more than one MRB may be established. A designated customer representative is considered a member of the MRB. The appropriate customer representative is notified of all MRB meetings.

When the volume of nonconforming material is small, a MRB structure may not be warranted. In this case the contractor may opt for a "tiger team" approach to each significant nonconformity. For any alternative to an MRB, the contractor will demonstrate all requirements of this clause 8.1.2 are met by the alternative approach.

8.1.2.1 Disposition Authority

The MRB is the only contractor constituted board authorized to determine, or recommend disposition of nonconforming material as specified in the contractor's directive documents. Directive documents may also extend limited disposition authority to the PR and MR functions

8.1.2.2 Delegation of MR Authority

The contractor may delegate all or a specified part of MR authority to a subcontractor or supplier. Delegation shall be with customer agreement and be specified in the contract. The contract shall also specify under what conditions the delegation is revoked.

8.1.3 Material Dispositions

8.1.3.1 Use-as-is Dispositions

Requirements pertaining to use-as-is dispositions are as follows:

a. When a designated customer technical representative resides at the contractor, subcontractor, or supplier's facility, the representative shall participate in all use-as-is

dispositions as a member of the MRB or equivalent approach as discussed in the implementation box found in 8.1.2. If no designated customer technical representative is on site, the customer reserves the right to subsequently review such dispositions

b. All use-as-is dispositions shall include any recommended documentation change and the method for accomplishing the change (i.e., design change, changes to technical documentation including drawings, specifications, and technical orders, or recommended changes to customer specifications)

c. Contractual agreements shall exist with the System Program Office (SPO) and Defense Contract Management Agency (DCMA) for a customer representative to participate in use-as-is dispositions

8.1.3.2 Repair Dispositions

Requirements pertaining to repair dispositions are as follows:

a. When a designated customer technical representative resides at the prime contractor, subcontractor, or supplier's facility, the customer shall participate in all repair dispositions as a member of the MRB or equivalent body as discussed in the implementation box found in 8.1.2. If no designated customer technical representative is on site, the customer reserves the right to subsequently review such dispositions

b. Instructions for reprocessing of material after completion of repair and before its release shall be included in the SRP or other repair procedure. These procedures shall include the requirement for contractor inspection and test as required

c. Contractual agreements shall exist with the SPO and DCMA for a customer representative to participate in repair dispositions

Implementation. The purpose of repair is to reduce the effect of the nonconformance. Repair is distinguished from rework in that the characteristic after repair still does not completely conform to the applicable drawings, specifications, or contract requirements. Except for standard repair procedures (see below), proposed repairs approved by the customer are authorized for use on a one-time basis only.

8.1.3.2.1 Standard Repair Procedures (SRP)

SRPs allow a repair disposition to be made by PR rather than MR (clauses 8.1.1 and 8.1.2). The contractor shall implement measures to detect repeated nonconformities requiring repair, track their frequency, and establish a documented technique for setting the threshold for establishing a SRP. The threshold may depend on a number of factors such as frequency of occurrence, severity of the nonconformity, cost to redesign to eliminate the nonconformity, etc. The SRP shall be used when it is a cost-effective approach for addressing a repeated nonconformity. Requirements pertaining to the approval and use of a SRP include the following:

a. The SRP shall be developed by the contractor, reviewed and concurred by the MRB or equivalent body as discussed in the implementation box found in 8.1.2

b. The SRP shall be used only if the government, as a member of the MRB (or equivalent body), concurs and approves of the SRP

c. Approval of a SRP shall include the establishing of the duration of use and/or frequency of use before the SRP must be re-evaluated

d. The contractor shall maintain records detailing the dates of use and number of applications of the SRP

e. The contractor shall review SRPs periodically to ensure that they are complete, up-to-date relative to current process capability and state-of-the-art, and are being properly applied under the conditions defined for their use

Implementation. This standard suggests that a proactive method to address repeated nonconformities is to install a system that can detect repeated nonconformities. Often this is a subjective process and therefore, cannot be fully implemented by an automated system. Repeated nonconformities may be detected by similar failure points, similar repair procedures, or operator or inspector observation.

Sometimes work instructions are created by copying and pasting repair steps from a previous and similar repair. The weakness in this nondocumented method is copying and pasting is subject to errors, particularly if the copying is not done from a common source. If a significant effort is being made to copy and paste repair processes, the contractor should implement a standard repair to assure the repair is well thought out and consistently applied.

8.1.3.3 Scrapped Material

Scrapped material shall be conspicuously identified and controlled to preclude its subsequent use in a contract item unless otherwise approved by the customer.

8.2 Identification and Segregation of Nonconforming Material

When material is found to be nonconforming, it shall be conspicuously marked or tagged (or otherwise identified if marking or tagging is not practical) and positively controlled to preclude its unauthorized use in production. Nonconforming material to be submitted to the MRB shall be moved to a controlled area designated for storage of nonconforming material unless not practical due to size, configuration, environmental requirements, or other conditions authorized by the customer. The designated area shall be protected to preclude unauthorized removal of nonconforming material.

8.3 Control of Nonconforming Material

The contractor shall establish and maintain a system which shall identify, segregate (or control if segregation is not practical), and properly dispose of nonconforming material and shall ensure that cost-effective, positive corrective action is taken to prevent, minimize, or eliminate nonconformances. The system shall work toward continual improvement of quality and productivity through the initiation and monitoring of Quality Improvement Programs (QIPs).

8.4 Discrepancy Reporting

8.4.1 Discrepant Products

Nonconforming products shall be identified and processed in accordance with the contractor's procedures for controlling nonconforming products. The contractor shall report the receipt of any nonconforming products to the responsible supplier.

8.4.2 Discrepant Purchase Documents

Products received that conform to requirements of the purchase document, but fail to conform to the latest applicable engineering revision, shall be placed in "hold status" pending resolution of the conflicting purchase/engineering documents. Subsequent handling of the product, if nonconforming, shall be in accordance with the contractor's established procedures. The contractor shall notify the customer representative when the decision is made to continue processing nonconforming items.

8.5 Quality Audits

The contractor shall schedule and conduct audits of personnel, procedures, and operations, to determine if the QPP is properly implemented. The activity shall include audits of subcontractors and sub-tier suppliers. Each audit shall include examination of selected operations and documentation; evaluation of actual operations as compared with established requirements; recommendations, as appropriate, for remedial and preventive action; and follow-up to assess results of action taken. Audits shall include examination of articles, materials, and products to verify the effectiveness of the contractor's effort and product conformance to technical and contractual requirements. The appropriate customer representative shall be informed of audits scheduled and be allowed to participate in the audits

a. Audit plans, checklists, and other such tools shall be prepared to guide the audit. They shall be based on customer and contractor requirements

b. The results of audits in each area shall be documented with appropriate responses for correction of deficiencies. Management action shall be taken to ensure effective correction of the reported deficiencies

8.6 Metrics

8.6.1 Construction of Metrics

Metrics used to report quality status shall be constructed to be actionable, consistent, and used to make decisions.

Implementation: Contractors have found it useful to publish with the metric the following: person who assembled the metric, explanation of the calculations involved when they are not obvious, conclusion, and recommendation for action, if any.

8.6.2 Cost of Poor Quality

The contractor and subcontractors shall collect nonconformance cost data consisting of a minimum of scrap, rework, and repair costs as specified in the contractor’s directive documents. The cost data shall be used by management to establish measurement parameters for evaluation of manufacturing planning and manufacturing process in attaining suitable yield and product quality.

Implementation. Cost of poor quality is different than cost of quality. The latter includes costs of prevention, appraisal, internal and external failure. Contractors have found it difficult to determine these costs as the data must be retrieved from data systems which are often not compatible with each other and under the control of different functions. These functions will include but are not limited to timekeeping, engineering, quality, manufacturing, test, supplier management, and finance.

Cost of poor quality addresses those costs associated solely with poor quality and frequently contractors will keep records on this measure, particularly if a major investigation is involved. Cost of poor quality may be estimated using unit costs or total resources. In the former case the cost estimate requires the number of times the deficiency occurs coupled with the average cost for correcting the deficiency. In the latter case, the cost estimate requires the total resources consumed in a category plus the percentage of the resources consumed when a deficiency occurs.

8.6.3 Analysis of Records

The contractor shall conduct analysis of quality records for the purpose of:

a. Identifying quality trends and taking appropriate corrective action

b. Establishing confidence levels for products, processes and suppliers by the review of objective evidence of conformance

c. Increasing the efficiency of inspection and manufacturing operations by the judicious consolidation of records or operations when it can be demonstrated that such records or operations are of no value to the program or can be combined in a more effective manner

8.6.4 Minimum Data Summarization Requirements

Nonconformance data shall be recorded to enable summarization of the quantity of nonconforming items, number of recurrences, cause determinations, corrective actions, dispositions, and nonconformance. Nonconformance data shall be used by the CAB to determine the need for and effectiveness of corrective action. The format of the data and the frequency of preparation shall be at the discretion of the contractor but in no case shall the preparation be less frequent than quarterly. As a minimum, the following data shall be included:

a. Quantity of nonconforming items

b. Number and type of nonconformances

c. Number and type of dispositions

d. Cause determinations

e. Type of corrective actions and status

f. Delinquent corrective actions

g. Nonconformance costs

h. Trend information and analysis thereof

8.7 Addressing Systemic Issues

The contractor shall implement measures to detect, and processes to correct systemic issues that affect product quality. Systemic issues may involve any of the dispositions listed in 8.1.2 (d). Repair

procedures, while they return product to functional performance, affect negatively customer satisfaction and measures shall be taken to reduce the number of repeated repairs.

8.7.1 Corrective Action Board (CAB)

The CAB shall ensure that an effective corrective action system is in place to improve product quality. This function shall be performed through review and analysis of nonconformance data. The CAB shall ensure that records of causes of nonconformances, trends, and individual causes acted upon are maintained and that individual records and summaries of actions taken are prepared. The appropriate customer representative shall be notified of all CAB meetings and be invited to attend.

8.7.1.1 CAB Authority and Responsibilities

The CAB shall:

a. Have authority to ensure implementation of corrective actions to all contractor operations affecting product quality

b. Have the authority to require investigations and studies by other contractor organizations necessary to define essential corrective actions that will result in reducing nonconformance costs and reducing the amount of nonconformances

c. Ensure that documentation required by clause 4.4.5 is maintained

d. Ensure that summary data of nonconformances and associated costs are analyzed and areas of high potential payoff, adverse trends, exceeding control limits, or out-of-control recurrence of nonconformances are thoroughly investigated to identify appropriate corrective actions and to identify potential QIPs

e. Be responsible for ensuring that follow-up systems are maintained to ensure that timely and effective corrective actions are taken

f. Ensure that reviews of nonconformance data and PR and MRB disposition decisions are conducted periodically to determine that PR and MRB actions are effective and in compliance with the requirements of this standard

g. Ensure that a process evaluation is accomplished and that specific corrective actions are taken to bring the process back into acceptable limits when control limit techniques are used and analysis of cumulative data for an applicable nonconformance reveals that the established limits are being or will be exceeded

h. Ensure that the contractor documents nonconformances and monitors: yield requirement development, documentation, and evaluation; the process control system for compliance; process improvement activity as it relates to trends; and recurrences of nonconformances when corrective action is required due to inadequate process controls or control limit techniques and until such time as it has been demonstrated that the corrective action has been effective

8.7.2 Failure Review Boards

Failure Review Boards (FRBs) shall operate essentially the same as MRBs with the exception that they may be chaired by other contractor functions. FRB requirements are discussed in more detail in TR-RS-2007-00013, *Reliability Program Requirements for Space Systems.* Details on the failure analysis to be presented at FRB are given in TR-RS-2013-00009, *Parts, Materials, and Processes Control Program for Space Vehicles* and TR-RS-2011-00011, *Parts, Materials, and Processes Control Program for Expendable Launch Vehicles.*

8.8 Customer Rights

The customer reserves the right to: review all contractor procedures developed to implement this standard; observe PR, CAB, and QIP activities; participate in MRB activities; and review documents or other data required by this standard.

8.9 Process Variability Control

The contractor's organization shall participate in the development of techniques used to control process variability, including processes that affect product key characteristics. This shall consist of the independent evaluations by qualified personnel of design, manufacturing, and test processes as well as the accompanying documentation. As a minimum, the following shall be included in a process variability control activity:

a. Critical quality characteristics are identified, measured, and verified

b. Sufficient data is collected to support the variability analysis

c. Procedures and methods are established for preventive and corrective actions, and feedback is provided to design, manufacturing, and test operations

d. Process variability is measured by noting document uniformity, defect creation, time studies, incoming and delivered product acceptance or other appropriate studies. The measurement may, but usually does not, involve a statistical analysis of results

Implementation. Process variability control is often a part of preventive action and may involve very simple process improvements. For example, if a planning organization produces work instructions which are noted to have significant variability, the organization may conduct a root cause analysis and find that planners are not trained to a common standard. By implementing better training and establishing planning templates, greater uniformity of the work instructions is achieved.

8.9.1 Statistical Process Control (SPC)

Although infrequently used in the space hardware production industry, when appropriate SPC may be used. If it is applied to the control of processes or product, control limits shall be based upon documented history of the process capability. Limits shall be established statistically or by other methods which take into account the accepted variability of the product. Data in the form of control charts or process histograms shall be available to production workers in real time.

8.9.1.1 Out of Control Action Plan (OCAP)

The contractor shall document in an OCAP the actions to be taken when an out of control condition (OCC) is detected. These actions shall include as a minimum the definition of an OCC, the functional members of the team designated to investigate an OCC, when this activity will occur, and what actions the team is empowered to take. The OCAP shall document in particular the steps to be taken should the process need to be halted because of excessive OCCs.The process shall be documented prior to the full implementation of the SPC application.

Attachment 1: Quality Program Plan Data Item Description (DID)

DATA ITEM DESCRIPTION	
Title QUALITY PROGRAM PLAN	Identification Number TBD
Description/Purpose 3.1 This plan describes how the Quality Program will be conducted. It describes the specific techniques and activities to be performed and their integration and development in conjunction with other specified related plans. The principal use of this item is to provide a detailed description of a contractor's program to be accomplished under the contract.	
Approval Date (YYMMDD) TBD	Office of Primary Responsibility (OPR) SMC/NRO
Application/Interrelationship 7.1 This DID contains the format and content preparation instructions for the Quality Program Plan required by Paragraph 4.2.1 of the Quality Space and Launch Requirements Addendum to AS9100C. 7.2 This data item is provided to permit preparation of a separate Quality Program plan or integration of the plan within a consolidated Product Assurance/System Effectiveness Program Plan (PA/SEPP) which normally includes Software Quality, Reliability, Parts, Materials and Processes, and other related disciplines. Cost, system integration and methods of contracting are considerations in preparation of a single PA/SEPP or separate Coordinated Plans.	
Approval	
Preparation Instructions 10.1 Reference Documents. Aerospace TR-RS-2015-00003/SAE AS 9100C. 10.2 Methods and Techniques. The plan shall outline the methods and techniques for incorporating quality into design and for conducting a comprehensive quality program in accordance with the contract scope of work and specifications as listed in the contract. It shall portray how quality will be achieved in sufficient detail to include schedule, technique, procedures and responsibilities for each specific task. 10.3 Program Definition. The plan shall define the scope and depth of the contractor's efforts, including the management, organization, staffing, planning and technical aspects, and the relationship of the Quality Program to the contractor's other administrative and technical programs. The plan shall include a statement that it does not take precedence over AS 9100, Supplemental Quality Requirements standard, or other contractual requirements. 10.4 Special Considerations. The plan shall identify unusual or special areas of hardware and data products requiring unique quality assurance considerations; and detail or reference the unique quality assurance procedures that will be utilized to assure a quality product. The plan shall detail the inspection work in process to substantiate compliance of critical and major attributes which will not be substantiated by subsequent inspections. 10.5 Flow Chart Requirements. The plan shall contain flow charts showing the flow of supplies, materials, and data together with the quality assurance functions performed. All areas of contract performance shall be specified; for example, design, development, fabrication, processing, assembly, inspection, test, maintenance, packaging, shipping, storage and site installation. 10.6 Matrix Requirements. The plan shall contain a cross-index (Matrix) which identifies the relationship between the program plan, applicable contract specifications and standards, and contractor policies, procedures, instructions, and controls used to implement the requirements. 10.7 Detailed Requirements. The Quality Program Plan shall address the requirements of AS9100, Revision C and the Supplemental Quality Requirements of this standard.	

SMC Standard Improvement Proposal

INSTRUCTIONS

1. Complete blocks 1 through 7. All blocks must be completed.
2. Send to the Preparing Activity specified in block 8.

NOTE: Do not use this form to request copies of documents, or to request waivers, or clarification of requirements on current contracts. Comments submitted on this form do not constitute or imply authorization to waive any portion of the referenced document(s) or to amend contractual requirements. Comments submitted on this form do not constitute a commitment by the Preparing Activity to implement the suggestion; the Preparing Authority will coordinate a review of the comment and provide disposition to the comment submitter specified in Block 6.

SMC STANDARD CHANGE RECOMMENDATION:	**1. Document Number** SMC-S-003	**2. Document Date** 2015

3. Document Title	Quality Space and Launch Addendum to AS9100C

4. Nature of Change
(Identify paragraph number; include proposed revision language and supporting data. Attach extra sheets as needed.)

5. Reason for Recommendation

6. Submitter Information

a. Name	**b. Organization**
c. Address	**d. Telephone**
e. E-mail address	**7. Date Submitted**

8. Preparing Activity

Space and Missile Systems Center
AIR FORCE SPACE COMMAND
483 N. Aviation Blvd.
El Segundo, CA 91245
Attention: SMC/EN